

## The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health

Department of Public Health 250 Washington Street, Boston, MA 02108-4619

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MONICA BHAREL, MD, MPH

Tel: 617-624-6000 www.mass.gov/dph

September 18, 2015

New England Treatment Access, Inc. Mr. Arnon Vered Executive Director 5 Forge Parkway Franklin MA 02038

Re:

Request for a Waiver

Dear Mr. Vered:

On September 2, 2015, New England Treatment Access, Inc. ("NETA") submitted a written request for a waiver from 105 CMR 725.105(C)(2)(a) as it applies to heavy metals and pesticides, and 105 CMR 725.105(E)(2)(g) and 105 CMR 725.105(E)(3)(i), labeling requirements for finished plant material and cannabis concentrate. In your request, you represented that Massachusetts laboratories were currently unable to test to the levels required by the Department. You have submitted testing reports from the laboratory used by NETA that supports your representation.

I find that compliance would cause undue hardship to NETA and patients, that NETA will institute compensating features acceptable to the Department of Public Health (the "Department") and that with those compensating features, non-compliance does not jeopardize the health or safety of any patient or the public. NETA's September 2, 2015 request for a Waiver from 105 CMR 725.105(C)(2)(a), only as it applies to heavy metals and pesticides, as well as the labeling requirements for finished plant material and cannabis concentrates in 105 CMR 725.105(E)(2)(g) and 105 CMR 725.105(E)(3)(i), is granted effective as of the day of this letter. This extended waiver is subject to the conditions set forth below:

1. For three (3) months from the date of this letter (the "Waiver Term"), or until such time that NETA has demonstrated to the Department's satisfaction that it can fully comply with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Marijuana Dispensaries and Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries (collectively, the "Protocols"), whichever occurs earlier, it may only dispense a maximum of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate (1 gram of cannabis concentrate = 5.16 grams of finished plant

material), or a combination of both that would not exceed a total of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate, and must supply each qualifying patient or caregiver with instructions that for finished plant material, a maximum of 2 grams may be consumed per day, and for cannabis concentrate, a maximum of 1.13 grams be consumed per day;

- 2. During the Waiver Term, NETA shall continue to conduct testing in compliance with the Protocols for finished plant material and cannabis concentrate for all substances listed in 105 CMR 725.105(C)(2)(a), including heavy metals and pesticides, and submit the results to the Department;
- 3. During the Waiver Term, NETA shall take all necessary steps to ensure that the presence of heavy metals in finished plant material and cannabis concentrate is as minimal as possible, but shall not be required to meet the levels specified in Exhibit 4 of Section 7 of the Protocol for Sampling and Analysis of Finished Medical Marijuana and Marijuana-Infused Product for Massachusetts Registered Marijuana Dispensaries;
- 4. Consistent with NETA's representation in its request that it does not use the plant-growth regulators and pesticides identified in the Protocol, NETA shall not use any of the plant-growth regulators and pesticides identified in the Protocol during the Waiver Term;
- 5. During the Waiver Term, NETA shall be subject to increased inspections to ensure compliance with the conditions of this waiver, including requests for additional testing and information regarding the testing capabilities of any independent laboratory selected for testing by NETA;
- 6. NETA must maintain records available for inspection by the Department that it only dispenses a maximum of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate (1 gram of cannabis concentrate = 5.16 grams of finished plant material), or a combination of both that would not exceed a total of 4.23 ounces of finished plant material or the dry weight equivalent of cannabis concentrate, and must supply each qualifying patient or caregiver with instructions that for finished plant material, a maximum of 2 grams may be consumed per day, and for cannabis concentrate, a maximum of 1.13 grams be consumed per day;
- 7. Labels for all marijuana finished plant material and cannabis concentrate produced during the Waiver Term shall disclose that product may not meet the established standards for heavy metals and pesticides:
  - "WARNING: This product may not meet the established standards for heavy metals and pesticides."
- 8. The Department reserves the right to revoke or modify this waiver at any time should it determine that NETA, or any of its dispensary agents, fail to comply with the terms and conditions of the waiver, or if the Department finds that the waiver no longer serves the

interests of the public health or safety, including in the event that the Department develops updated Protocols pursuant to 105 CMR 725.105(C)(2).

The Department anticipates that NETA will work expeditiously to resolve the issues that have led to the request for an extended waiver. If, however, NETA determines it cannot do so within the extended Waiver Term, a request for any additional waiver must be received by the Department 14 days prior to the expiration of the current waiver. Please contact <a href="mailto:RMDcompliance@state.ma.us">RMDcompliance@state.ma.us</a> with any questions regarding this waiver.

Sincerely,

Monica Bharel, MD, MPH

Commissioner

Massachusetts Department of Public Health